Remarks:

Claims 1, 2, 4–7, 9–11, 13, 14, and 17–21 are currently pending with claims 1, 18, and 20 being independent. Claim 1 is amended. Declarations Under 37 C.F.R. § 1.132 signed by Rhetah Kwan, Debi Whitson, Wayne W. Moore, and Dr. Harvey Serota are submitted with this Amendment as evidence supporting the arguments set forth below.

The Declarations

Amended Declaration of Rhetah Kwan

Rhetah Kwan's Declaration was submitted with the last Response. The Examiner found Ms. Kwan's Declaration insufficient because there was allegedly (1) "no showing that others of ordinary skill in the art were working on the problem, and if so, for how long"; and (2) "no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem." Ms. Kwan has revised her Declaration to address these alleged insufficiencies set forth by the Examiner. Additionally, Applicant submits with this Amendment additional Declarations that address the Examiner's concerns, and such Declarations will be discussed in further detail below.

As stated in the Response, Ms. Kwan is an uninterested party with twelve years of experience in the electronic medical record industry implementing electronic medical record software systems and providing training and support services to companies using the systems. Her career in the electronic medical record industry culminated in 2002, the year after the present Application was filed.

Ms. Kwan first attests that her twelve years of experience was with MedicaLogic, Inc., a company specializing in the development, deployment, and support of electronic medical records ("EMRs"). Applicant submits that MedicaLogic, Inc. has since been purchased by General Electric Health and is now sold under the name GE Centricity. GE Centricity is one of the top EMR systems in the United States. (See Declaration of Wayne W. Moore, ¶ 2).

Ms. Kwan attests that "inputting of patient information into an EMR has always been a necessary but problematic obstacle to use of EMRs and has existed from at least as early as 1990." Ms. Kwan further attests in ¶ 11 that she recognized a need, at least as early as 1990, for a more efficient manner of inputting patient information into the patient's EMR. Ms. Kwan states that she addressed the problem of inputting patient information in to the EMR by educating EMR system users on the demands of manual submission. Given these statements by Ms. Kwan, Applicant respectfully submits that Ms. Kwan's Declaration establishes that others were working on the problem of inputting patient information into an EMR since at least 1990, and thus, there was a long-felt but unsolved need.

Ms. Kwan's Declaration further illustrates that the invention as recited in claim 1 of the Application would not have been obvious to a person skilled in this art at the time the invention was made. For example, as indicated in Paragraph 15 of Ms. Kwan's Declaration, Ms. Kwan was not aware that the functionality recited in claim 1 could be performed.

Declaration of Debi Whitson

Ms. Whitson's Declaration was submitted with the last Response. The Examiner found Ms. Whitson's Declaration insufficient because there was allegedly no evidence that the commercial success was a result of heavy advertising or promotion, and further, there was allegedly no evidence

of market share. Ms. Whitson has revised her Declaration to address these alleged insufficiencies set forth by the Examiner.

At ¶ 5, Ms. Whitson attests that she has not heavily advertised or promoted PatientLink™, and in fact, her only efforts to promote PatientLink have been renting a booth at a trade show twice a year. The vast majority of Ms. Whitson's customers come from prior customer referrals or word-of-mouth.

Additionally, at ¶ 6, Ms. Whitson attests that her sales have significantly grown every year since she first began marketing and selling PatientLink™ in the second half of 2000. In the first two full years of sale, Ms. Whitson sold approximately 50 systems. By the fifth year, she had sold approximately 66 systems, and in the past two years, she has seen a significant increase due to word-of-mouth and customer referrals. In particular, she sold an average of approximately 157 systems in each of 2006 and 2007. This amounts to an approximate 137% increase in sales in years 2006 and 2007.

Although the Examiner stated that evidence of market share was necessary, as the Examiner can appreciate, Ms. Whitson does not have figures for her competitor's sales so as to determine her derived market share. However, the Federal Circuit has stated that sales figures alone are sufficient evidence of commercial success: "Although sales figures coupled with market data provide stronger evidence of commercial success, sales figures alone are also evidence of commercial success." *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1352, 1361, 52 U.S.P.Q.2d 1294 (Fed. Cir. 1999), *citing to Cable Elec. Prods., Inc. v. Genmark, Inc.*, 7701 F.2d 1015, 1027, 226 U.S.P.Q. 881, 888 (Fed. Cir. 1985) ("'[I]nformation [about market share] might bolster the existence in fact of any commercial success . . . demonstrated by [mere sales data] . . . .'"). Therefore, Applicant respectfully requests that the Examiner appropriately consider the evidence of commercial success submitted by

Applicant, including the Declarations of Debi Whitson, Wayne W. Moore, and Dr. Harvey Serota (the latter two discussed below).

Declaration of Harvey Serota, MD, FACC

Dr. Serota's Declaration evidences the nexus between sales of the PatientLink™ software, which embodies the claims of the present application, to the features claimed. In particular, Dr. Serota attests that his medical practice, which sees approximately 10,000 patients per year (¶ 2), evaluated approximately five EMR systems (¶ 3), but ultimately chose GE's Centricity system because PatientLink™ was offered as add-on software that was operable with the Centricity system (¶ 4). Further, Dr. Serota attests that PatientLink™ allows his medical practice to input patient information directly into the EMR using a scantron type of card on which the patient enters his/her information. (¶ 5). Finally, Dr. Serota estimates that PatientLink™ saves his practice approximately 10 minutes per patient because an individual that is authorized to view the patient data, such as a nurse or doctor, need not manually enter the information into the EMR. (¶ 6).

Declaration of Wayne W. Moore

Mr. Moore's Declaration evidences the nexus between sales of the PatientLink™ software, which embodies the claims of the present application, to the features claimed. Mr. Moore is Sales Manager for an authorized partner of GE's Centricity EMR. (¶ 2). In this capacity, Mr. Moore educates potential customers about PatientLink™ as add-on software to GE's Centricity EMR system. (¶ 3). Mr. Moore attests that consumer responses to PatientLink™ have been "overwhelmingly positive," and that PatientLink™ is seen as a "huge benefit to the practices we serve and is a truly unique advantage." *Id.* Mr. Moore further attests to data entry into an EMR

being "one of the biggest challenges physicians face when switching from a paper chart to an EMR." (¶ 4).

Supporting Reference Material

Applicant submits as Exhibit A a journal article from May-June 1997, published in the Journal of the American Medical Informatics Association, and written by CJ McDonald, a medical professor at the Indiana University School of Medicine. The article provides a lengthy discussion on the use of EMRs and the barriers to implementation by the medical community. Additionally, the article provides solutions to overcoming the barriers. In particular, the author suggests that there needs to be a standardized method of "merging data from many sources into one EMR." (Ex. A, p. 5). In this aspect, the author is discussing obtaining data from laboratories, pharmacies, physician dictation, other medical offices, etc., and merging the information into one EMR. To accomplish this, the author suggests taking advantage of existing communication standards, such as certain internet protocols (p. 5), HL7 (p. 6), and DICOM (p.6). Interestingly, however, the author notes that HL7 "provides the structure . . . for interchanging patient information between source systems like a laboratory, dictation and pharmacy systems data repositories . . . ." (Ex. A, p. 6). However, at no instance does the author suggest using HL7, or, for that matter, any existing protocol, to input patient information ***received directly from a patient*** into an EMR. In fact, in the section entitled "The Ultimate EMR," the author states that "checklist symptom questionnaires" provided to patients are problematic. (Ex. A, p. 8). The author further states that "[t]he ultimate EMR promises to capture whatever patient data is needed to perform any EMR task." (Ex. A, p. 7). However, to accomplish this, the author focuses on how best to create an EMR that captures patient information ***inputted by physicians***, as opposed to patients. Thus, the author clearly is not compelled to use HL7 as a means for inputting patient information received from the patient into an EMR.

Exhibit A provides evidence that a medical researcher and professor in the field of capturing and maintaining medical information, and further authoring a journal article that is directly discussing how best to create a workable EMR, appreciates that there is a problem on how to input patient information into an EMR, i.e. appreciates that there is a long-felt need. Dr. McDonald was at least working on the problem from as early as May–June 1997, and based on statements by Dr. McDonald throughout the article, the problems of inputting patient information into an EMR were known well before then. Therefore, Applicant submits that Exhibit A provides evidence that others of ordinary skill in the art were working on the problem of inputting patient information into an EMR from at least as early as 1997, that those of ordinary skill in the art were aware of EMRs and the HL7 protocol, and that those of ordinary skill in the art were unable to solve the problem.

Exhibit B is another journal article from May 2004 discussing "problems in entering data" into EMRs. (Ex. B, p. 2). The author states that "[d]ata entry has always been a major obstacle to healthcare professionals' acceptance of electronic records." The author further discusses the problems with entering patient information. In the section entitled "Capturing the patient's narrative," the author discusses the need to obtain patient information from the patient, if possible: "Data should be acquired as close to the source as possible." The author characterizes an "ideal electronic records system" as one that allows the clinician to input narratives effortlessly "at the patient's bedside or at the office desk."

Thus, the author in Ex. B, as with the author in Ex. A, believed that the solution to inputting patient information into an EMR was for the clinician to input the information – and not the patient. There is no reference of record that suggests that patient information ***obtained from and entered by the patient on a scantron form*** could be inputted into an EMR. There clearly was a problem of inputting patient information, but prior art references of record focused on how best to obtain the patient information from the clinician, and not from the patient directly. There still existed the

problem of how best to obtain the patient information as automatically as possible and without reliance on a highly-trained clinician.

Response to the Examiner's "Response to Arguments"

At page 13 of the last Office Action, the Examiner states that claims 1, 4, 6, 18, and 20 "recite combinations which unite old elements with no change in their respective functions and which yield predictable results." Applicant respectfully and vigorously disagrees. The present invention changes the function of the HL7 protocol and uses it in a way that has never been done before. HL7 was previously primarily used to transmit laboratory information. Other uses, as evidenced by Exhibit A, were to communicate notes, referrals, scheduling information, nursing notes, problems, clinical trials data, and master file records. (See also p. 14 of Office Action noting that HL7 could be used for data exchange between scheduling, billing, medical records and laboratory systems). None of these pieces of information are the same as patient information obtained directly from a patient. Applicant respectfully submits that the type of information the HL7 protocol is used to communicate, absent the present invention, is completely different than information obtained from a patient who is marking a scantron with his/her information. Using the HL7 protocol to transmit information from one platform to another, i.e., from a laboratory's computer system to a medical office's computer system, is impossible unless both parties have an interface to handle the "conversion" from one platform to another and the information conforms to the type of information HL7 is intended to be used for. If the information is the type of information HL7 is not intended to be used for, then the protocol cannot handle or work with the information; it simply does not recognize the information. This is true for any software protocol, whether it be in the medical field, accounting, etc.

The present invention overcomes these obstacles by using the HL7 protocol for a purpose that it was not built to do. The present invention essentially "tricks" the HL7 protocol to believe it is working with a laboratory and with laboratory types of information. The invention thus offers an interface that can receive the patient information directly from the scantron card and arrange the information into a form commonly accepted by EMR systems, namely an HL7 form. Once again, Applicant respectfully submits that taking information that is already in a form commonly accepted by HL7 is not the same as taking information that is completely foreign to the accepted form for HL7, arranging the information into a form that the HL7 protocol believes is acceptable, and thus allowing automatic inputting of the information into an EMR.

This is all the more evident in the prior art of record applied by the Examiner. For example, the system of Kimak does not import information into a patient's electronic medical record, as recited in claim 1, but rather uses electronic medical records already created by physicians. (¶ 68). The Kimak system gleans information from the medical records to present to users, and even stores entire copies of medical records on physicians' computer systems, but does not import information into electronic medical records. Therefore, Kimak and Kraftson considered in combination fail to teach any form of importing information received from a patient to a patient-specific electronic medical record, much less "arranging the data stream [from a scanning type machine] into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record."

At page 15 of the Office Action, the Examiner states that importation of the patient information into the EMR is not positively recited. Applicant has amended the independent claims to recite such. Additionally, the Examiner states that there is "nothing in the current claim language that precludes any imported data from being added to a medical record created by physicians." Applicant's representative is unsure what the Examiner is arguing here, and therefore, has not addressed the Examiner's argument. Further explanation is respectfully requested.

With respect to importation of the information, the Examiner further argues at pages 16-17 that Kimak "discloses sending or communicating the formatted data to an assigned location (e.g. an electronic medical record interfaee engine) and importing or adding the information into the patient's patient-specific medical record . . . ." Applicant respectfully disagrees. Kimak does not disclose importing information into an EMR, but rather sending an entire EMR alrcady held by a medical organization to another medical organization. This is the reason why the "match/merge algorithms" are required in Kimak, namely if two duplicate medical records are received by a particular medical organization, then the Kimak system dedupes the medical records to remove copies. (See ¶ 68). This is another very important distinction between Kimak and the present invention.

The system of Kimak includes "an electronic medical record *registry* system" (¶ 33, emphasis added), wherein the system accesses electronic medical records from "a plurality of medical service provider databases" and presents information from those records to "registered point of service care providers" as a complete medical history of the patient. (Kimak, ¶¶ 47, 74, 75; FIG. 3). While Kimak discloses "merging" medical records (¶ 12), this merging operation involves merging information from multiple medical records into a single "view" or user interfaee element, and does not involve creating a new medical record. Kimak expressly discloses, for example, that "the merging does not result in creation of a storage location for a new record." (¶ 35). Moreover, when electronic medical records are communicated to the main registry database, the medical records are sent in their entirety and replaced by new, updated records when necessary. (¶¶ 77–81). Thus, information is never imported into a medical record, as recited in elaim 1.

Applicant respectfully submits that the Examiner is incorrectly interpreting Kimak as creating an electronic medical record and populating the EMR with information obtained from other medical organizations. In fact, Kimak is not doing this; instead and as discussed above, Kimak is creating a database of EMRs received from disparate sources (¶ 5) and allowing this information to be viewed by others in a database "providing a completed patient history." (See ¶ ¶ 0048 and 0068). At pages

18-19 of the Office Action, the Examiner states that "Kimak discloses how patient data is obtained from disparate sources, appropriately formatted, and added [to] the main registry." This is incorrect, however, because (1) the Examiner is leaving out the remainder of the Kimak system, namely that the information is obtained from a server; and (2) Kimak does not obtain patient information but rather an EMR that contains patient information. In essence, the Examiner is applying Kimak as importing patient information into an EMR when it, in fact, does not. Instead, Kimak uses HL7 to reformat an already existing EMR into a database that can be viewed by multiple persons.

Additionally, Applicant submits that it is much simpler to interface an existing EMR with a particular software system than it is to interface the information contained in the EMR with the software system. Even when discussing the advantages of the Kimak invention, Kimak does not refer to the created database as an EMR itself, but rather a database for multiple EMRs that provide a particular patient's immunization history. (See ¶ 0013 (referring to combining EMRs across databases); ¶ 0047 (describing the focus of the Kimak system as allowing systems to share information); ¶ 0048 (referring to assembling EMRs from multiple sources); and ¶ 0070 (referring to providing a complete immunization history by obtaining all of a patient's EMRs)). Therefore, contrary to the Examiner's assertion, Kimak does not teach importing specific, discrete information obtained from a patient into an EMR.

At page 17 of the Office Action, the Examiner asserts that the remote servers of Kimak from which the information is obtained can be construed broadly enough to encompass server owners/operators, and physicians, as well as patients. First, Applicant notes that the claim language used is obtaining information from a patient, and not from a user. Second, the claim recites that the scan card provided to the patient is used to obtain the information, and thus, the claim recites that the information is obtained from the patient. Moreover, Applicant disagrees that Kimak's alleged teaching of obtaining information from a server teaches or suggests the recited obtaining patient

information from a patient. If there is particular claim language that the Examiner considers appropriate, Applicant would welcome the Examiner's insight.

At page 23 of the Office Action, the Examiner states that "claims 1 and 6 fail[] to distinguish Applicant's use in the instant invention from the traditional well-known use of HL7 or the use described in the applied prior art." Applicant respectfully disagrees. The prior art of record is clear that HL7 has only been used for laboratory information and scheduling, physician dictation, or other types of administrative information. Never has HL7 been used to obtain a patient's past medical history, including family history, surgeries, diseases, etc. A laboratory test stating that a patient tests positive for blood lead levels, for example, is not the same type of information as whether the patient has had heart surgery. The Examiner is trying to apply laboratory information, that is very limited in scope and function, to all types of patient information that would be obtained by a clinician. This is improper, and Applicant respectfully requests the Examiner reconsider her rejection.

In sum, Applicant submits that the Examiner has not established a *prima facie* case of obviousness, as required by MPEP § 2142. According to the MPEP, "[t]he key to supporting any rejection under 35 U.S.C. 103 is a clear articulation of the reasons why the claimed invention would have been obvious" (MPEP § 2142 (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ 2d 1385, 1396 (2007))). Additionally, "[t]he Federal Circuit has stated that 'rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'" (MPEP § 2142 (citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ 2d 1385, 1386 (2007) (quoting *In re Kahn* with approval)). Furthermore, the MPEP states that, when the prior art fails to teach or suggest all of the claim limitations, "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art" (MPEP § 2141(III)). Such an explanation must include "articulated

reasoning with some rational underpinning to support the legal conclusion of obviousness" (MPEP § 2142). Thus, to establish a *prima facie* case of obviousness when the prior art fails to teach each limitation of the claimed invention, the Examiner must present a rationally supported reason as to why one of ordinary skill in the art would find the claimed invention, including the missing limitation, obvious in view of the cited prior art.

Applicant respectfully submits that the Examiner has not addressed the inadequacies of the Kimak reference in allegedly teaching or suggesting arranging a data stream simulating the format of an HL7 protocol, wherein the data stream comprises a patient's written responses regarding the patient's symptoms, and importing the information into an EMR. Applicant respectfully requests the Examiner explain in detail how Kimak discloses this, without mere reference to paragraphs of Kimak, given that Applicant has rebutted the Examiner's allegations with a detailed discussion of the teachings of Kimak.

Finally, throughout the Office Action, the Examiner supplies the following as the reason why it would have allegedly been obvious to one of ordinary skill in the art to combine Kraftson with Kimak: "it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teachings of Kraftson to use paper machine-readable questionnaires to obtain patient information," because "[o]ne would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice." (OA, pages 5-6). This is exactly the type of "conclusory statement" the Supreme Court recently rejected as a grounds for forming a sustainable obviousness rejection, and the Examiner's assertion clearly falls short of the required "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 2007 WL 1237837 at *13. The Examiner fails, for example, to identify why a person skilled in this art would believe that the proposed combination would result in the alleged benefits.

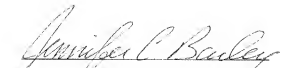
For at least these reasons, a person of ordinary skill in this art would have no reason to combine Kimak and Kraftson as proposed by the Examiner.

Conclusion

For at least the reasons set forth above, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson. The Examiner has further failed to identify a reference or combination of references that teaches or suggests each limitation of the independent claims. Therefore, Applicant respectfully submits that claims 1, 2, 4–7, 9–11, 13–14, and 17–21 are now in allowable condition and requests a Notice of Allowance.

In the event of further questions, the Examiner is urged to call the undersigned. Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,
HOVEY WILLIAMS LLP

By: 

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